## REMARKS

The Office Action mailed February 15, 2008 has been carefully considered and the following is responsive thereto. Claims 1-27 are pending in the application.

### Non-Statutory Obviousness-Type Double Patenting Rejection

At pages 2-3 of the Office Action, the Examiner maintained the rejection of claims 1 and 2 on the ground of non-statutory obviousness-type double patenting over claims 44 and 45 of copending application Serial No. 10/824,688 for the reasons set out in the Office Action mailed March 6, 2006.

Applicants again request that the rejection be held until such time as notice of patentable subject matter has been received in the applications. An appropriate terminal disclaimer will be filed at that time if necessary.

### Rejections under 35 USC 103

At pages 3-4 of the Office Action, the Examiner maintained the rejection of claims 1-17, 20, 21, and 23-27 under 35 USC 103(a) as obvious over Gennadios (U.S. Patent 6,214,376) for the reasons set out in the Office Action mailed March 6, 2006. Claims 18, 19 and 22 were separately rejected under 35 USC 103(a) as obvious over Gennadios (U.S. Patent 6,214,376) for the reasons set out in the Office Action mailed March 6, 2006. The Examiner's remarks relating to the rejections appear to be the same as his remarks in the Office Action mailed November 11, 2006. Briefly, the Examiner indicated that Applicants' arguments based on structural differences between kappa-2 carrageenan and kappa and iota carrageenans disclosed in Gennadios are not sufficient to overcome the rejections because kappa-2 carrageenan and kappa and iota carrageenans possess common structural characteristics and properties.

Applicants again traverse these rejections and request reconsideration thereof based upon the arguments of record, which are incorporated herein by reference, as well as the comments set forth herein.

On October 17, 2007, Applicants' representative Paul Fair conducted a personal interview with Examiners Leigh Maier and Everett White in regard to the rejections of claims 1-27 over the Gennadios patent. As noted in the Examiner Interview Summary Record, mailed on October 22, 2007, Applicants' representative Paul Fair discussed the outstanding rejections and the differences between the prior art and the claimed invention. More specifically, in conjunction with the discussion of the prior art, Mr. Fair provided background information on the chemistry and properties of carrageenan in general and kappa-2 carrageenan, iota carrageenan and kappa carrageenan in particular (such as known gelling properties and varying degrees of sulfation), and referred to Falshaw, Food Hydrocolloids 15: 441-452, 2001, and Bixler, Food Hydrocolloids 15: 619-630, 2001, both of which are listed on the Examiner Interview Summary Record, to assist the Examiners' understanding of both the cited prior art and the claimed invention. As noted in the Examiner Interview Summary Record, the Examiner agreed to reconsider the properties of kappa-2 carrageenan and the prior art rejections. The Examiner's remarks in the present Office Action, however, do not acknowledge the personal interview with Mr. Fair, nor do they address the points discussed during the interview. Applicants respectfully request that the Examiner specifically address the points discussed in the interview.

The Examiner appears to rely on Applicants' specification as stating that all carrageenans are structurally and functionally similar without providing any additional support for this position or providing clear guidance as to where in the Applicants' specification (at pages 4-7) such support purportedly exists. Applicants respectfully request that the Examiner provide further explanation of this position, and point out specific supporting passages in the specification.

Applicants submit that the present application does not support the position that all carrageenans are structurally and functionally similar. Quite the contrary. The present specification, for example, details the known structural differences between the various carrageenans in the molar ratios of 3:6AG-2S to 3:6AG content (e.g., see the present specification at page 5, first full paragraph) and further notes, for example, that iota and kappa carrageenans are known to be "gelling carrageenans" whereas kappa-2 carrageenan is known to be "weakly gelling" (e.g., see the present specification at page 7, first full paragraph).

Furthermore, in the paragraph bridging pages 7-8 of the present specification, Applicants further note in the present specification that it is generally recognized that kappa-2 carrageenan has a lower water gel strength than kappa carrageenan, iota carrageenan and simple physical mixtures of kappa and iota carrageenans. It is clear from the specification and, for example, the Witt reference, previously submitted in an Information Disclosure Statement, that the ability of carrageenans to form gel films varies significantly depending on the type of carrageenan. Applicants again respectfully submit that the present specification does not support the position proffered by the Examiner.

In view of the differences in structure and in gelling properties generally believed to exist between kappa-2 carrageenan and both kappa and iota carrageenans, persons skilled in the art would not have found the presently claimed invention, i.e., a delivery system comprising a thermoreversible, homogeneous, gel film comprising kappa-2 carrageenan and an active substance and methods for the manufacture thereof, obvious in view of the disclosures of Gennadios. Gennadios is directed to film forming compositions useful for soft capsules comprising *kappa carrageenan*. There is nothing in Gennadios that suggests to one skilled in the art the desirability of a delivery system comprising a gel film comprising kappa-2 carrageenan.

Kappa carrageenan is known to be weakly gelling and, based on traditional water gel strength and textural measurement, kappa-2 carrageenan is known to have a low water gel strength when compared to kappa carrageenan, iota carrageenan or physical mixtures of kappa and iota carrageenan. Persons killed in the art, therefore, would have no reasonable expectation that kappa-2 carrageenan could be used for delivery system gel film applications. As the inventors here found, when kappa-2 carrageenan is used in making delivery systems comprising gel films, it demonstrates surprising film strength and mechanical integrity, well beyond expectations based on known molecular structuring with respect to water gels. It also demonstrates full compatibility with traditional film ingredients, such as starch, humectant, etc. This surprising film strength of kappa-2 carrageenan also allows carrageenan molecular weight control in order to better balance process viscosity and required film strength for mechanical

processing, such direction resulting in the capability to operate at lower moisture levels in the cast films while maintaining other essential film properties.

In summary, there is no disclosure or suggestion in Gennadios that a different type of carrageenan could be substituted for kappa carrageenan, much less a weaker gelling carrageenan such as kappa-2 carrageenan. Kappa-2 carrageenan has a much lower water gel strength than kappa carrageenan, iota carrageenan or physical mixtures of kappa and iota carrageenan. To the surprise of Applicants, however, kappa-2 carrageenan forms surprisingly strong gel films with film strength and mechanical integrity well beyond expectations based on known molecular structuring with respect to water gels. Accordingly, withdrawal of the rejections of claims 1-17, 20, 21 and 23-27, and 18, 19 and 22 as obvious under 35 USC 103 is respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 10884-00018-US from which the undersigned is authorized to draw.

Dated: May 15, 2008

Respectfully submitted,

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